

REMARKS

Claims 1-15, are pending in this application. Claim 15 has been added. Reconsideration and allowance of all claims are respectfully requested in view of the following remarks.

Drawings

The drawings are objected to by the Examiner under 37 CFR 1.83(a).

Reference numeral 19 has been added to Figure 1(a) to denote the fabric inserts. No new matter has been added. Thus, the Examiner is respectfully requested to acknowledge receipt of one (1) Replacement Sheet which includes a corrected Figure 1(a), which should obviate the drawing objection.

Claim Objections

Claims 1 and 14 are objected to because of informalities.

The claims have been amended to obviate any informalities noted by the Examiner.

Double Patenting

Claim 1 is provisionally rejected on the ground of nonstatutory double patenting over claim 1 of copending Application No. 11/271,752. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Without addressing the merit of this rejection, the Applicants will consider filing a terminal disclaimer upon an indication of allowable subject matter.

Claim Rejections Under 35 U.S.C. § 112

Claim 5 is rejected to under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 5 has been amended to correct for any indefiniteness noted by the Examiner.

Prior Art Rejections

Claims 1, 2, 5-11, 13, and 14 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kotula et al. (U.S. Patent No. 5,846,261).

Claims 3, 4, and 12 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kotula et al. (U.S. Patent No. 5,846,261).

Claims 6, 7, and 9 have been canceled without prejudice or disclaimer. Applicants respectfully traverse the rejection of Claims 1-5, 8, and 10-14 as follows.

Response to Prior Art Rejections

The Applicants respectfully submit that Kotula et al. do not teach or suggest an occlusion device including, at least among other things, a braiding of thin wires or threads given a suitable form by a molding and heat treatment procedure, having a proximal retention area and a distal retention area, a holder disposed in the distal retention area, wherein the ends of the wires or threads converge therein, a cylindrical crosspiece interposed between said proximal and distal retention areas, whereby the two retention areas are positioned on the two sides of a shunt to be occluded in a septum by an intravascular surgical procedure while the crosspiece transverses the shunt, and wherein the proximal retention area of the braiding exhibits a flaring toward a

proximal end, and wherein an edge of the proximal end lies flush with the septum, as recited in amended Claim 1.

Further, Kotula et al. do not teach or suggest a method of manufacturing an occlusion device including configuring a funnel-shaped hollow braiding by bundling said hollow braiding at a first distal end; allowing an opposite second proximal end to remain open; forming a proximal retention area at the open second end, and a distal retention area at the bundled first end, and interposing a cylindrical crosspiece between said proximal and said distal retention areas, wherein said proximal retention area of said braiding is flared towards the proximal end, as recited in amended Claim 10.

Rather, Kotula et al. disclose a braiding of wires for an occlusion device 140 which includes a uniformly formed configuration with two expanded diameter portions 142, 144, and a reduced diameter portion 146 in-between. The configuration is in a shape of a bulbous portion at the proximal end 142 and a planar portion at the distal end 144. Thus, the shapes of the proximal and distal and retention areas 6, 8 of the present invention are not taught or suggested by Kotula et al. Further, the crosspiece 10 of the present invention is joined to the proximal retention area 6 of the present invention, and not uniformly formed with the bulbous portion at the proximal end 142 in Kotula et al.

The shape of the present occlusion device has the advantages of adapting independently to the defect in the septum wall – independent of the diameter of the size of the defect to be occluded and independent of the thickness to the septum wall – such that no portion of the occlusion device protrudes into the plane of the septum wall having a defect on the proximal

side. Thus, the flared contouring at the proximal end of the proximal retention area of the braiding allows the proximal retention area to flatten completely against the lateral edge of the defect in the inserted state. With no need for a holder for bundled or merging braiding at the proximal retention area, no components of the present device protrude past the septum wall, which prevents components of the implant being in constant contact with blood – and causing thrombembolic complications.

Accordingly, the present invention is not anticipated by, nor obvious over Kotula et al., and the rejection of Claims 1 and 10 under 35 U.S.C. §102(b) should be withdrawn.

Further, with respect to Claim 8, Kotula et al. do not teach or suggest an occlusion device wherein the wires or threads of the braiding at the open end of the proximal retention area are looped back to a closed end of the distal retention area and secured at the distal retention area in the holder disposed in the distal retention area.

Rather, the devices disclosed by Kotula et al. are made from a tubular braiding where each braided end of the device is held together with a clamp. The ends of the wires of the braiding, held together with a clamp at the proximal retention area, are looped back to join in the other clamp, at the distal retention area. Thus, the wires of the braiding are not looped back in such a way that all the ends of the wires forming the braiding can be joined at the distal end by one clamp only, rather than in two clamps as disclosed in Kotula et al.

In contrast, the present invention discloses a hollow braiding where the wires forming the braiding are looped back and intertwine at the proximal end so that the ends of all the wires can be joined and tightened at one end (the distal end) in a single holder. To produce the

occlusion device in this manner is advantageous since this results in the proximal retention area of the braiding exhibiting a flaring toward the proximal end, as recited in Claim 7.

Thus, Claim 8 is not anticipated by, nor obvious over Kotula et al., and the rejection of Claim 8 under 35 U.S.C. §102(b) should be withdrawn.

Further, with respect to Claim 12, Kotula et al. do not teach or suggest a method of manufacturing an occlusion device wherein the wires and threads of the braiding at an outer edge of the flattened tulip shape of the open end of the proximal retention area are looped back to a closed end of the distal retention area and are bundled and secured there in the holder.

Rather, Kotula et al. are silent with respect to his feature as discussed above. The Applicants respectfully remind the Examiner that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (See MPEP §2143). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Furthermore, the Examiner is respectfully reminded that "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of

obviousness." (*In re Khan*, 441 F.3d 977, 988 (CA Fed. 2006) cited with approval in *KSR International Co., v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

Since the Examiner merely alleges that this feature is obvious and a matter of design choice, without providing a reference which discloses this feature, or without providing any rational underpinnings to support this conclusion, then the Examiner has not met his burden of establishing a *prima facie* case of obviousness over Kotula et al., and the Examiner's rejection of Claim 12 under 35 U.S.C. §103 should be withdrawn.

Further, since Claims 2-9, and 15, depend from Claim 1, and Claims 11-14, depend from Claim 10, they are also patentably distinguishable over Kotula et al. for the reasons cited above with respect to Claims 1 and 10.

If the Examiner believes that there is any issue which could be resolved by a telephone or personal interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

Amendment Under 37 C.F.R. § 1.111
U.S. Application No.: 10,551,687

Atty Dkt No.: 51006.213672
Customer Number 57362

Applicants hereby petition for any extension of time that may be required to maintain the pendency of this case, and any required fee for such an extension is to be charged to Deposit Account No. 50-0951.

Respectfully submitted,

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